

R.K. MEDICAL

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JUN 18 1996

510(k) SUMMARY

K 961389

"This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21CFR 807.92."

Applicant

R. K. Medical L. L. C.
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Contact

John A. Hutter, Plant Manager
or
George R. Krebs (President)

Date

April 4, 1996

Name of Device

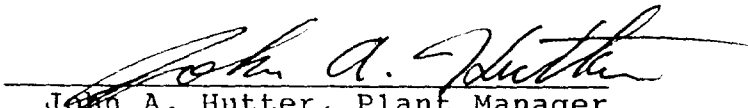
Common or Usual Name: Polypropylene Nonabsorbable Surgical Sutures
Classification Name: Suture, nonabsorbable, synthetic, Polypropylene

Polypropylene nonabsorbable surgical sutures, USP, manufactured by R. K. Medical L. L. C. are equivalent to Surgilene™ polypropylene nonabsorbable surgical sutures manufactured by Davis+Geck.

The Polypropylene sutures manufactured by R. K. Medical and D+G are monofilament and are dyed blue [phthalocyaninato (2-)] copper.

The Polypropylene nonabsorbable surgical sutures, USP are indicated for use in general soft tissue approximation and/or ligation, including use in cardiovascular, ophthalmic and neurological procedures.

Testing of suture diameter, suture length, knot pull tensile strength and needle attachment strength according to methods outlined in USP XXIII demonstrates that R. K. Medical polypropylene sutures meet or exceed U. S. P. specifications and are equivalent in terms of the above parameters to polypropylene sutures manufactured by Davis+Geck.


John A. Hutter, Plant Manager